Health Care Regulation Committee

Wednesday, January 25, 2006
9:30 AM - 12:00 PM
212 Knott Building

REVISED

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

January 25, 2006
9:30 AM - 12:00 PM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following bills:

HB 233 – Biomedical Research by Rep. Sands

HB 243 – Hearing Aid Specialists by Rep. Kendrick

HB 483 – Nursing Services by Rep. Garcia

III. Presentations on Discount Medical Plans/Cards

David Foy, Chief of Staff
Office of Insurance Regulation

Christopher Lang, President & CEO
Ageless Care

Nick Iarossi
Consumer Health Alliance

IV. Closing Remarks

V. Adjournment

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 233 Biomedical Research
SPONSOR(S): Sands and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 468

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell	Mitchell
2) Criminal Justice Committee			
3) Governmental Operations Committee			
4) Health Care Appropriations Committee			
5) Health & Families Council			

SUMMARY ANALYSIS

HB 233 creates s. 381.99, F.S., to establish the "Florida Better Quality of Life and Biomedical Research Act." The purpose of the Act is to foster medically ethical embryonic and human adult stem cell research in Florida. Currently, the state only supports research on adult stem cells and placenta or cord blood stem cells. The Act provides definitions of related stem cell terms and lists findings to support research in the state.

Developments in the fields of genetics, developmental biology, and information technology are moving stem cell research forward worldwide. Although the research is still in its infancy, experts believe this research could yield promising treatments and cures for certain debilitating diseases and injuries. Stem cell research is not without controversy. Questions persist about the costs and benefits of its use, the possible intended and unintended consequences of the research procedures, and the moral status of early life form from which stem cells are harvested.

To address the ethical issues involved in stem cell research, the bill creates two new councils to oversee stem cell research in Florida. The Biomedical Research Advisory Council is created to promote the advancement of embryonic and human adult stem cell research and the Biomedical Research and Ethics Oversight Council is created as a separate stem cell research institutional review board. The Act allocates $15 million dollars annually for 10 years, out of the existing Biomedical Research Trust Fund to provide for stem cell research.

The bill authorizes the donation of unused embryos from in vitro fertilization that would otherwise be thrown out with the informed consent of the donor.

The bill bans cloning for human reproduction and provides for a second degree felony. It also creates a second degree felony for sale or purchase of embryonic tissue for research purposes related to the Florida Better Quality of Life and Biomedical Research Act.

The estimated fiscal impact of the bill is $15 million dollars annually for 10 years. There is an additional fiscal impact for the Department of Health to implement the provisions of the bill. These costs are estimated at $744,830 in the first year and $593,171 in the second year. The bill sponsor intends to file an amendment to address the Department of Health costs.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides Limited Government – The bill creates two research councils to support adult and embryonic stem cell research in Florida. To accommodate the proposed bill the Department of Health would need to add staff, expand office space, and provide other resources to accommodate three full time employees. The estimated fiscal impact of the bill is $15 million dollars yearly for 10 years. There is an additional fiscal impact for the Department of Health to implement the provisions of the bill. These costs are estimated at $744,830 in the first year and $593,171 in the second year. The bill sponsor intends to file an amendment to address the Department of Health costs.

B. EFFECT OF PROPOSED CHANGES:

HB 233 creates s. 381.99, F.S., to establish the "Florida Better Quality of Life and Biomedical Research Act." The purpose of the Act is to foster embryonic and human adult stem cell research in Florida. Currently, the state only supports research on adult stem cells[1] and placenta or cord blood stem cells. The Act provides definitions of related stem cell terms and lists findings to support research in the state.

The bill creates two new councils to oversee stem cell research in Florida. The Biomedical Research Advisory Council is created to promote the advancement of embryonic and human adult stem cell research and the Biomedical Research and Ethics Oversight Council is created as a separate stem cell research institutional review board. The Act allocates $15 million dollars annually for 10 years, out of the existing Biomedical Research Trust Fund to provide for stem cell research. The bill requires a $15 million dollar appropriation annually for 10 years, from the Legislature.

The bill authorizes the donation of unused embryos from in vitro fertilization[2] that would otherwise be thrown out with the informed consent of the donor.

The bill bans cloning for human reproduction and provides for a second degree felony. It also creates a second degree felony for sale or purchase of embryonic tissue for research purposes related to the Florida Better Quality of Life and Biomedical Research Act.[3]

The effective date of the bill is July 1, 2006.

Biomedical Research Advisory Council

Section 381.99, F.S., creates the Biomedical Research Advisory Council to foster the advancement of embryonic and human adult stem cell research. The Council is charged with overseeing several business, research, and funding aspects of stem cell research in Florida.

This bill provides the Council with certain responsibilities which include:

- developing a recommendation for a private sector donated-funds program to encourage stem cell research in the state;
- examining and identifying specific ways to improve and promote embryonic and human adult stem cell research;
- developing a recommendation for a grant program to advance embryonic or human adult stem cell research; and
- monitoring research institutions receiving grant funding.

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[1] Adult stem cells are undifferentiated cells that are found in small numbers in most adult tissues.
[2] In vitro fertilization is provided for in ch. 742, F.S.
[3] Section 873.05, F.S., prohibits the advertising or sale of human embryos in general.

The bill requires the Council to submit an annual progress report on the state of biomedical research to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30, and specifies the content of the report.

The bill provides detailed requirements of Council members' experience in stem cell research, bioethics, private and public funding, and industry development. The Council will have 7 members with the Secretary of Health acting as chair. The President of the Senate, Speaker of the House of Representatives, Minority Leader of the Senate, and Minority Leader in the House of Representatives will all designate one Council Member. The Governor will appoint two members.

The bill requires the Department of Health (DOH) to provide administrative staff to assist the Council in developing a stem cell research grant application and review of grant applications, developing a written consent form to allow donation of leftover embryos from in vitro fertilization treatments, and to perform other functions as the Council requires.

Biomedical Research and Ethics Oversight Council

The bill creates a Biomedical Research and Ethics Oversight Council to review all embryonic or human stem cell research funded by the Biomedical Research Trust Fund. The Council will ensure adherence to ethical and safety guidelines and procedures established by the United States Department of Health and Human Services. Although the bill does not specifically indicate the Biomedical Research and Ethics Oversight Council as an institutional review board (IRB), per federal regulations[4] it would act as an additional institutional review board (IRB) under the Department of Health (DOH).[5]

The bill amends s. 381.86, F.S., to allow research conducted under the purview of the Biomedical Research and Ethics Oversight Council established by the bill, to be exempt from the existing Department of Health institutional review boards.[6]

The bill specifies that members must have knowledge and understanding of the ethical, medical, and scientific implications of embryonic and adult stem cell research. Members should also be familiar with related biomedical fields. Council members will serve 4 year terms commencing on October 1, 2006. Members may serve two terms. The first meeting of the Council should take place no later than November 1, 2006.

Members are required to meet at least twice annually, but no more than four times a year. The bill provides for members to be reimbursed for per diem and travel expenses. The bill would require DOH to submit a revision of the DOH Federalwide Assurance with the Office of Human Research Protections to add the Biomedical Research and Ethics Oversight Council to the committees of the DOH covered by the Department's Federalwide Assurance. From the perspective of federal regulations, the Biomedical Research and Ethics Oversight Council would serve as a third IRB within the Department of Health.

The proposed bill does not provide for professional and administrative staff support or administrative costs including daily operations, annual report preparation, application in-take or peer review, etc.

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[4] Federal regulations 45 C.F.R. 46 and 21 & 21 C.F.R. 50 and 56 require review of research involving stem cells. The Biomedical Research and Ethics Oversight Council would be required to review these protocols.

[5] The Department of Health operates under the Federalwide Assurance within the Office of Human Protections (FWA #00004682).

[6] The Department of Health currently operates IRB #1 & IRB #2 to process the volume of research applications.

Biomedical Research Trust Fund and Grants in Aid

The bill amends s. 20.435, F. S., to authorize the Biomedical Research Trust Fund to provide funding for the proposed, "Florida Better Quality of Life and Biomedical Research Act," s. 381.99, F.S. The Biomedical Research Trust Fund currently is used only for the purposes of the James and Esther King Biomedical Research Program and the Florida Center for Universal Research to Eradicate Disease (CURED).

Section 381.99, F.S., establishes that, beginning with the 2006-07 fiscal year, and for 10 consecutive years thereafter, no less than $15 million each year will be made available from the Biomedical Research Trust Fund for grants-in-aid for embryonic or human adult stem cell research.

The Biomedical Research Trust Fund receives $10.1 million yearly from the Chiles Endowment Fund ($4.1 million) and a distribution of alcoholic beverage tax collections ($6 million).[7] The bill would require an additional $15 million for 10 years to be appropriated from the General Appropriations Act.

The bill requires the Department of Health to require any applicant for a stem cell grant-in-aid to submit an application containing certain information. It provides that the advisory council (not the oversight council) will make recommendations to the Secretary of Health after considering the recommendations of the oversight council. The funding must only be used for embryonic or adult stem cell research. This includes, but is not limited to, adult stem cells derived from umbilical cord blood and bone marrow.

Donation of Unused Embryonic Stem Cell from In Vitro Fertilization

As part of s. 381.99, F.S., the bill authorizes donation of embryonic stem cells taken from donated embryos leftover from in vitro fertilization treatments that would otherwise be thrown away or destroyed. Under the bill a physician or other health care provider is directed to provide information to their patients that allow them to make an informed and voluntary choice about embryo disposition. If the patient decides to donate the unused embryos they must give written consent on a form provided by the Department of Health. The bill provides that embryonic and adult stem cell material may only be donated for research purposes with the informed consent of the donor. The bill creates a second degree felony to knowingly buy, sell, transfer, or obtain embryonic fetal tissue for the research purposes provided in the bill.

The bill also bans human reproductive cloning and creates a second degree felony for the offense.

Definitions

The bill provides a number of definitions relating to stem cell research. Currently, Florida statutes do not define any of the terms defined in HB 233. Section 381.99, F.S., of the bill provides definitions for adult stem cell, asexual reproduction, embryonic stem cells, human reproductive cloning, in vitro fertilization, oocyte, and stem cells.

Legislative Findings

HB 233 creates a rationale statement for supporting stem cell research in Florida. Section 381.99, F.S., provides the following legislative findings:

- An estimated 130 million Americans suffer from acute, chronic, and degenerative diseases and that there is an enormous potential for lifesaving treatment and therapy as a result of recent advances in biomedical research.
- Florida is unique among all states for its large projected net population increase within the next 20 years. This increase, in turn, raises significant health care concerns as a new, larger

[7] ss. 215.5602 and 561.121, F.S. & General Appropriations Act line item 536.

generation of retirees moves to Florida, resulting in a corresponding rise in the number of persons suffering from illnesses such as cancer, heart disease, Alzheimer's Disease, Parkinson's Disease, cerebral palsy, juvenile diabetes, atherosclerosis, amyotrophic lateral sclerosis, AIDS, spinal cord injuries, severe burns, osteoporosis, osteoarthritis, cystic fibrosis, muscular dystrophy, multiple sclerosis, macular degeneration, diabetic retinopathy, retinitis pigmentosa, cirrhosis of the liver, motor neuron disease, brain trauma, stroke, sickle cell anemia, and intestinal diseases.

- In order to maintain a high quality of life for all Floridians, research into stem cell regenerative therapies and treatment should be supported to give hope and relief to the millions of citizens who suffer in silence from degenerative and crippling diseases.
- To reduce the burden on the health care infrastructure, the state must shift its health care objectives from costly long-term maintenance toward prevention and cures.
- To bolster and advance Florida's burgeoning biotechnology industry, the state should provide funds and incentives for private research companies to work in the state.
- The state should advance the goal of scientific and academic discourse in our universities and help bring its public and private universities to the forefront in biomedical research and technology.
- It will benefit the economy of the state to create a wide array of new projects and high-paying jobs related to biomedical research.
- It will benefit the state to foster cooperation between the state's universities and private sector research in terms of jobs, resources, and academic discourse relating to biomedical research.
- The public funds provided under this section are intended to spur innovation and development in Florida's biotechnology sector, which will be used to treat debilitating chronic diseases.

CURRENT SITUATION

Overview

In the 20th century, life spans have increased and human health has improved dramatically in part due to new pharmaceutical drugs and medical treatments based on scientific research. Many of these treatments initially drew public concern, such as early testing and administration of vaccines and the replacement of sulfa drugs with antibiotics.

Currently, proponents of early human stem cell research profess it to be as important as these earlier medical advances. Developments in the fields of genetics, developmental biology, and information technology are moving stem cell research forward worldwide.[8] Although the research is still in its infancy, experts believe this research could yield promising treatments and cures for certain debilitating diseases and injuries.

Stem cell research is not without controversy. Questions persist about the costs and benefits of its use, the possible intended and unintended consequences of the research procedures, and the moral status of early life forms from which stem cells are harvested.[9]

Institutional Review Boards

The Department of Health (DOH) institutional review boards (IRBs) review all state funded research involving human subjects, including research involving stem cells under s. 381.86, F.S. The Secretary of Health appoints board members, chairs, and co-chairs to the DOH institutional review boards. DOH maintains compliance with all applicable federal regulations and guidance. The DOH institutional review boards (IRBs) meet twice a month.

[8] United Kingdom, Belgium, Sweden, Israel, India, Singapore, China, Japan, South Korea and South Africa are some of the world leaders in stem cell research.

[9] Early Stem Cell Research, Center for Practical Bioethics, Spring 2005.

DOH currently staffs three other legislatively created research programs with advisory councils. The James and Esther King Biomedical Research Program, the Florida Cancer Center, and the Florida Center for Universal Research to Eradicate Disease (CURE) all currently operate under the Department of Health. The James and Esther King Biomedical Research program is similar to the proposed Florida Better Quality of Life and Biomedical Research Act.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state uses funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The research conducted may include stem cell related research.

Federal Regulations

In November 2001, President George W. Bush created The President's Council on Bioethics "to advise the President on issues that may emerge as a consequence of advances in biomedical science and technology."[10] In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

There are four primary sources for embryonic stem cells: existing stem cell lines, aborted or miscarried embryos, unused in vitro fertilized embryos, and cloned embryos. Current federal policy limits federally funded research to research conducted on embryonic stem cell lines created before August 2001.[11] Federal funding of research involving cloning for the purpose of reproduction or research is prohibited. However, there is no federal law banning human cloning altogether. The Food and Drug Administration has claimed authority over the regulation of human cloning technology as an investigational new drug (IND) and stated that at this time, they would not approve any projects involving human cloning for safety reasons, but Congress has not passed legislation confirming the FDA's authority to prohibit cloning.[12]

Stem Cell Legislation in Other States

Many state legislatures have been particularly interested in the stem cell debate. In 2005 states considered over 170 bills on embryonic and adult stem cell research. More than a dozen states will carry over legislation, and others will consider new bills. Should embryonic stem cell research be legal? Should state funds support it? Should the state fund adult stem cell research instead? These are some of the questions lawmakers are asking nationwide in 2006.[13] Both California and New Jersey have taken the lead in supporting stem cell research. Both states have struggled with regulatory issues.

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[10] Executive Order #13237.

[11] There are currently more than 60 existing different human embryonic stem cell lines that have been developed from excess embryos created for in vitro fertilization with the consent of the donors and without financial inducement. These existing lines are used in approximately one dozen laboratories around the world (in the United States, Australia, India, Israel, and Sweden).

[12] State Embryonic and Fetal Research Laws, National Conference of State Legislatures, 2005.

[13] Challenges in 2006, Contemplating Stem Cell Research, National Conference of State Legislature, January, 2006.

California has chosen to create a mini-National Institute of Health (NIH) to oversee research, whereas New Jersey has centralized research.

BACKGROUND

Stem Cells 101

Stem cells are unique and unspecialized cells. The purpose of stem cells in the adult body is to replace cells normally lost due to age, injury, or disease. Two properties that make stem cells unique from other cells:

1. Stem cells can divide thousands of times without error and without breaking down. Scientists can cause one stem cell to produce hundreds of identical stem cells in what is called a line.

2. Stem cells can differentiate into a variety of different cells. Scientists can induce stem cells to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.[14]

There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells they can differentiate into and generally only develop into the cell types of the tissue from which they were isolated.[15] Embryonic stem cells are more flexible and can be triggered to produce a range of specialized cells. After an egg is fertilized, it begins to divide from one cell into two, then from two cells into four, and so on. In the first few divisions, each embryo cell contains the ability to make all the cells in the human body. As the embryo continues to divide, the cells begin to specialize into particular organ cells. It is for this reason that the most "useful" stem cells are those that have not yet passed the first few divisions.[16] This quality is important because it permits such stem cells to be used to address a variety cures and treatments for disease.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed.

Reproductive Cloning

Reproductive cloning is the cloning of a human embryo for the purposes of initiating a pregnancy. The debate over reproductive cloning heated up when "Dolly" the sheep was successfully cloned in 1997. Federal funding for cloning research is prohibited and 13 states have passed laws prohibiting reproductive cloning.[17] Several others have banned state funding for reproductive cloning. Florida is one of the many states that have not weighed in on the issue. The proposed legislation bans reproductive cloning.

Ethical Issues

A central ethical issue surrounding embryonic stem (ES) cell research involves the status of the human embryo. In general, the stances that people hold on this issue depend on two factors: (1) beliefs on the status of the embryo, and (2) the context in which embryos are acquired and used. In terms of the status of the fetus, stances vary from "embryos are human individuals and should never be used for

[14] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu.
[15] Stem Cell Basics. National Institutes of Health. http://stemcells.nih.gov/index.asp.
[16] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. www.DNApolicy.org.
[17] National Conference of State Legislatures, State Human Cloning Laws, 2005.

research," to "embryos are a mere cluster of cells and may be created for the sole purpose of research." The majority of people gravitate to a position between the two stances, holding for example that embryos are "more than just cells," but they do not have the same status as a fetus or baby, and can therefore be used to derive stem cells for research.[18]

In terms of the context in which embryos are acquired, stances also vary. For many people who believe that human life begins at conception, it is wrong to create embryos for the purpose of destroying them; however it is acceptable to use already existing embryos that are left over from in vitro fertilization procedures and would be discarded anyway. This principal is referred to as the "nothing is lost" principle and means if an embryo is not going to be used for its original purpose of reproduction and would be discarded in the future, science should be allowed to make use of the embryo prior to its destruction, for research that might benefit people who are alive and suffering from a disability or illness.[19]

Florida Center for Universal Research to Eradicate Disease (CURED)

Florida's Center for Universal Research to Eradicate Disease (CURED) was created by the Florida Legislature in its 2004 Regular Session. Section 381.855, F.S., established the program and created an advisory council to provide policy recommendations to the Legislature. The program is appropriated $250,000 from the annual administrative expenses allocated to the James the Esther King Biomedical Research program. The fiscal year 2005-2006 budget did not include any full-time staff positions.

CURED seeks to coordinate, improve, expand and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread use. It seeks to promote research programs that identify cures to cancer, heart and lung disease, diabetes, autoimmune disorders and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

As part of the enabling legislation for CURED, the program is charged with holding an annual biomedical technology summit in Florida. CURED is also directed to monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. However, given its limited budget, CURED has not yet held an annual biotechnology summit. However, one is planned for summer 2006. CURED also has not started monitoring the supply and demand of stem cells in Florida and does not plan to in the immediate future.[20]

Scripps Florida Funding Corporation

SB 6E passed during the 2003E legislative session created s. 288.955, F.S., which creates a not-for-profit organization known as the Scripps Florida Funding Corporation (corporation) for the purpose of receiving, holding, and investing, administering, and disbursing funds appropriated by the Legislature for the establishment and operation of a state-of-the-art biomedical research institution in this state. The funding corporation was responsible for negotiating and executing a contract with the Scripps Research Institute to accomplish this goal.

Currently, Florida is moving ahead with the creation of a Scripps Research Institute. It is likely the Institute will be built in one of the south Florida communities.

C. SECTION DIRECTORY:

Section 1. Amends s. 20.435, F.S., to expand the use of the Biomedical Research trust fund to include a proposed new statute, s. 381.99, F.S.

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[18] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu.
[19] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. www.DNApolicy.org.
[20] Annual Report of the Advisory Council of The Florida Center for Universal Research to Eradicate Disease, 2005.

Section 2. Amends s. 381.86, F. S., to provide that research involving human embryonic and adult stem cells be reviewed pursuant to the provisions of s. 381.99, F.S., instead of the existing Institutional Review Boards.

Section 3. Creates s. 381.99, F.S., the "Florida Better Quality of Life and Biomedical Research Act," provides definitions, lists legislative findings, creates the biomedical research advisory council, creates the biomedical research and ethics oversight council, provides for a stem cell grant application with the Department of Health, authorizes the donation of unused embryonic stem cells from in vitro fertilization, provides a second degree penalty for the buying or selling of embryonic stem cells, and provides a second degree felony for human reproductive cloning.

Section 4. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Estimated Department of Health Institutional Review Board Revenue

Estimated Revenue	1st Year	2nd Year (Annualized/Recur.)
IRB Revenue		
20 initial reviews****	$30,000	$30,000
10 amendments year one	$5,000	$0
20 amendments year two	$0	$10,000
20 continuing reviews	$0	$10,000
Total Estimated IRB Revenue	**$35,000**	**$50,000**

* FTEs are computed w/ 28% fringe and 3% base salary increase for second year.
** Estimates based on James and Esther King Biomedical Research Program cost. First year is higher for one time only development costs.
*** Mostly additional education for members and office supplies.
**** Estimated based on awarding 20 three-year grants at a total of $750,000 per grant. The number of amendments is a guess.

2. Expenditures:

Estimated Department of Health Expenditures

Estimated Expenditures	1st Year	2nd Year (Annualized/Recur.)
Salaries*		
0.5 Senior Attorney @$50,000	$32,000	$32,960
0.5 Legal Secretary@32,000	$40,960	$42,189
1 Program Administrator @55,000	$70,400	$72,512
0.5 Program Assistant @32,000	$20,480	$21,094
0.5 IRB Admin. Assistant @32,000	$20,480	$21,094
Subtotal	**$184,320**	**$189,850**
Expense		
0.5 FTE Professional, limited travel	$11,060	$5,978

0.5 FTE Support Staff	$8,148	$3,380
1 FTE Professional, maximum travel	$21,393	$10,783
0.5 FTE Professional, limited	$11,060	$5,978
0.5 FTE Support Staff	$8,148	$3,380
Annual Report	$20,000	$20,000
Application & peer review process**	$472,809	$330,700
Program marketing, info. Dissemination	$5,000	$5,000
Travel for two councils	$7,644	$7,873
Additional IRB expense***	$30,250	$30,250
Subtotal	**$595,510**	**$423,322**
Net Expenditures	**$744,830**	**$593,171**

* FTEs are computed w/ 28% fringe and 3% base salary increase for second year.
** Estimates based on James and Esther King Biomedical Research Program cost. First year is higher for one time only development costs.
*** Mostly additional education for members and office supplies.
**** Estimated based on awarding 20 three-year grants at a total of $750,000 per grant. The number of amendments is a guess.

Trust Fund Expenditures

Estimated Expenditures	1st Year	2nd Year (Annualized/Recur.)
	$ 15 million	$15 million

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that researchers at private universities and institutions receive research grants there is a direct positive impact on the private sector. The program may generate monies from patents, and licensure/royalty income depending on the outcome of such research. To the extent that funded research leads to commercial products the biotechnology and pharmaceutical industries will benefit, as will residents if jobs are created. Additionally, the bill may increase the likelihood that treatments and or cures are found for many chronic illnesses.

D. FISCAL COMMENTS:

The proposed bill does not specifically allow or disallow using part of the proposed $15 million for operating costs. A similar program administered by the Department of Health (DOH), the James and Esther King Biomedical Research Program, allows no more than 15% of each year's appropriation for administrative costs.

Although not mentioned in the proposed bill, additional staff and resources will be needed to support the Biomedical Research and Ethics Oversight Council. Unless DOH is allowed to use up to 15 percent of the $15 million for administrative expenses the department would be faced with absorbing the entire cost of providing this support using its allotted general revenue. DOH would need to add staff, expand

office space, and provide other resources to accommodate three FTEs, including a 0.5 FTE attorney for the increased legal work associated with the project.

The criminal Justice Impact Conference has not met to consider the prison bed impact of this bill on the Department of Corrections. The two penalties created by the bill may add an additional fiscal impact due to prison costs.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule making authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Biomedical Research and Ethical Oversight Council

The bill does not make clear that the Biomedical Research and Ethical Oversight Council created in s. 381.99, F.S., is an institutional review board and must comply with federal and state regulations governing research involving humans. The term "institutional review board" is a generic term used to describe the entity in an institution that is responsible for ensuring the health and safety of persons participating in research. It may be called by a different name, but it is still an institutional review board. The lack of clarity in the bill further complicates the ability of the Council to charge for research review. Currently under s. 381.86(5), F.S., the Department of Health (DOH) institutional review board (IRB) may assess fees to support the review of human subject research.

In section s. 215.5602, F.S., there is another body named the Biomedical Research Advisory Council; however, the bill does not amend s. 215.5602, F.S. The bill should provide a unique name for the advisory council it creates to avoid confusion.

Section 381.99, F.S., specifies that the Biomedical Research and Ethical Oversight Council will meet at least twice annually, but no more than four times annually. According to the Department of Health, institutional review boards (IRBs) generally receive application for reviews and amendments on an ongoing basis. Limiting the number of times an IRB committee may meet, would create unnecessary delays in research because the research can not continue until approval is received.

Grant-in-Aid Funding

Previous bills creating a grant program have used the same or similar language as established in, s. 215.5602, F.S., for the James and Esther King Biomedical Research Program. One key component of the grants disseminated for the James and Esther King Biomedical Research Program is an unbiased peer review process. According to the Department of Health, a peer review process is critical to the success of a grant-in-aid program. The grant-in-aid funding program in the Florida Better Quality of Life and Biomedical Research Act does not provide for an unbiased peer review process.

The bill sponsor intends to file amendments to remedy drafting issues.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to biomedical research; amending s. 20.435, F.S.; revising uses for funds credited to the Biomedical Research Trust Fund; amending s. 381.86, F.S.; providing that the Institutional Review Board within the Department of Health shall not review certain research within the jurisdiction of the Biomedical Research and Ethics Oversight Council; creating s. 381.99, F.S., the Florida Better Quality of Life and Biomedical Research Act; providing definitions; providing legislative findings; creating the Biomedical Research Advisory Council; providing for criteria, appointment, and terms of members; authorizing reimbursement for per diem and travel expenses; providing duties of the advisory council, including a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives; requiring the Department of Health to provide administrative support; creating the Biomedical Research and Ethics Oversight Council to regulate research procedures and enforce ethical guidelines; providing for criteria, appointment, and terms of members; authorizing reimbursement for per diem and travel expenses; providing duties of the oversight council; providing for a grants-in-aid program for the purpose of conducting embryonic or human adult stem cell research; providing that grants-in-aid shall be provided through funds in the Biomedical Research Trust Fund; restricting the use of such funds for research on certain stem cells; providing requirements

with respect to the disposition of human embryos following infertility treatment; requiring the Department of Health to develop and maintain on its Internet website a consent form for the donation of certain embryos; prohibiting purchase or sale of embryonic fetal tissue for research purposes; prohibiting certain acts relating to human reproductive cloning; providing penalties; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

(1) The following trust funds are hereby created, to be administered by the Department of Health:

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program as specified in ss. 215.5602 and 288.955 and the purposes of the Florida Better Quality of Life and Biomedical Research Act as specified in s. 381.99. The trust fund is exempt from the service charges imposed by s. 215.20.

2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of

the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

3. Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended may be certified by the Governor for up to 3 years following the effective date of the original appropriation.

4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.

Section 2. Subsection (1) of section 381.86, Florida Statutes, is amended to read:

381.86 Institutional Review Board.--

(1) The Institutional Review Board is created within the Department of Health in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review ~~all~~ biomedical and behavioral research on human subjects which is funded or supported in any manner by the department except for research within the jurisdiction of the Biomedical Research and Ethics Oversight Council, which shall be reviewed pursuant to the provisions of s. 381.99.

Section 3. Section 381.99, Florida Statutes, is created to read:

381.99 Florida Better Quality of Life and Biomedical Research Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Better Quality of Life and Biomedical Research Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Adult stem cell" means an undifferentiated cell found among differentiated cells in a tissue or an organ that can renew itself and can differentiate to yield the major specialized cell types of the tissue or organ.

(b) "Asexual reproduction" means reproduction not initiated by the union of oocyte and sperm.

(c) "Embryonic stem cells" means cells obtained from the undifferentiated inner mass of an early stage embryo.

(d) "Human reproductive cloning" means the practice of creating or attempting to create a human being by transferring the nucleus from a human cell into an egg cell from which the nucleus has been removed for the purpose of implanting the resulting product in a uterus or substitute for a uterus to initiate a pregnancy.

(e) "In vitro fertilization" means a technique in which oocytes are fertilized by sperm outside of a woman's body resulting in organisms that are not genetically identical to any one existing human.

(f) "Oocyte" means an immature egg cell of the human ovary.

(g) "Stem cells" means undifferentiated cells which retain the potential to differentiate into some or all other cell types.

(3) LEGISLATIVE FINDINGS.--The Legislature finds that:

(a) An estimated 130 million Americans suffer from acute, chronic, and degenerative diseases and that there is enormous potential for lifesaving treatment and therapy as a result of recent advances in biomedical research.

(b) Florida is unique among all states for its large projected net population increase within the next 20 years. This increase, in turn, raises significant health care concerns as a new, larger generation of retirees moves to Florida, resulting in a corresponding rise in the number of persons suffering from illnesses such as cancer, heart disease, Alzheimer's Disease, Parkinson's Disease, cerebral palsy, juvenile diabetes, atherosclerosis, amyotrophic lateral sclerosis, AIDS, spinal cord injuries, severe burns, osteoporosis, osteoarthritis, cystic fibrosis, muscular dystrophy, multiple sclerosis, macular degeneration, diabetic retinopathy, retinitis pigmentosa, cirrhosis of the liver, motor neuron disease, brain trauma, stroke, sickle cell anemia, and intestinal diseases.

(c) In order to maintain a high quality of life for all Floridians, research into stem cell regenerative therapies and treatment should be supported to give hope and relief to the millions of citizens who suffer in silence from degenerative and crippling diseases.

(d) To reduce the burden on the health care infrastructure, the state must shift its health care objectives from costly long-term maintenance toward prevention and cures.

(e) To bolster and advance Florida's burgeoning biotechnology industry, the state should provide funds and incentives for private research companies to work in the state.

(f) The state should advance the goal of scientific and academic discourse in our universities and help bring its public and private universities to the forefront in biomedical research and technology.

(g) It will benefit the economy of the state to create a wide array of new projects and high-paying jobs relating to biomedical research.

(h) It will benefit the state to foster cooperation between the state's universities and private sector research in terms of jobs, resources, and academic discourse relating to biomedical research.

(i) The public funds provided under this section are intended to spur innovation and development in Florida's biomedical technology sector, which will be used to treat debilitating chronic diseases.

(4) BIOMEDICAL RESEARCH ADVISORY COUNCIL.--There shall be established a Biomedical Research Advisory Council.

(a) The advisory council shall consist of the Secretary of Health, who shall act as chair, and six additional members, who shall be appointed as follows:

1. Two persons appointed by the Governor, one of whom shall be an academic researcher in the field of stem cell research and one of whom shall have a background in bioethics.

2. One person appointed by the President of the Senate, who shall have a background in private sector stem cell funding

and development and public sector biomedical research and funding.

3. One person appointed by the Speaker of the House of Representatives, who shall have a background in private sector stem cell funding and development and public sector biomedical research and funding.

4. One person appointed by the Minority Leader of the Senate, who shall have a background and experience in either public or private sector stem cell research and development.

5. One person appointed by the Minority Leader of the House of Representatives, who shall have a background and experience in business and financial investments.

Members shall serve for terms of 2 years each commencing on October 1, 2006. No member shall serve for more than two consecutive 2-year terms. All initial appointments must be made by October 1, 2006. The first meeting shall take place no later than November 1, 2006. Members shall meet at least twice annually, but no more than four times annually. Members shall serve without compensation but shall be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The members of the advisory council shall work to provide an environment fostering the advancement of embryonic and human adult stem cell research. The advisory council shall:

1. Develop a donated funds program for recommendation to the Secretary of Health, to encourage the development of funds other than state appropriations for embryonic and human adult stem cell research in the state.

2. Examine and identify specific ways to improve and promote for-profit and not-for-profit embryonic and human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing embryonic and human adult stem cell related businesses, recruiting new embryonic and human adult stem cell related businesses to the state, and recruiting scientists and researchers in such fields to the state and state universities.

3. Develop a biomedical research grant program for recommendation to the Secretary Health, which shall provide grants-in-aid to eligible institutions for the advancement of embryonic or human adult stem cell research.

4. Develop, no later than December 1, 2006, an application for grants-in-aid under this section for recommendation to the Secretary of Health for the purpose of conducting embryonic or human adult stem cell research.

5. Receive applications from eligible institutions for grants-in-aid on and after December 1, 2006, and provide to the Secretary of Health recommended grant awards.

6. Monitor the stem cell research conducted by eligible institutions that receive such grants-in-aid.

(c) The advisory council shall submit an annual progress report on the state of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30. The report must include:

1. The amount of grants-in-aid awarded to eligible institutions from the Biomedical Research Trust Fund.

2. The recipients of such grants-in-aid.

3. The current status and progress of stem cell research in the state.

4. A list of research projects supported by grants-in-aid awarded under the program.

5. A list of publications in peer-reviewed journals involving research supported by grants-in-aid awarded under the program.

6. The total amount of biomedical research funding currently flowing into the state.

7. New grants for biomedical research that were funded based on research supported by grants-in-aid awarded under the program.

8. All other materials the council deems advisable to include.

(d) Advisory council members shall disclose any conflict of interest or potential conflict of interest to the Secretary of Health.

(e) The Department of Health shall provide administrative staff to assist the advisory council in developing the application for the grants-in-aid, reviewing such applications, making recommendations to the advisory council, preparing the written consent form described in paragraph (7)(b), and performing other administrative functions as the advisory council requires or as is deemed necessary.

(5) BIOMEDICAL RESEARCH AND ETHICS OVERSIGHT COUNCIL.--There shall be established a Biomedical Research and Ethics Oversight Council.

(a) The oversight council shall consist of seven members, of which the Secretary of Health shall act as chair. The additional members shall be appointed as follows:

1. Two persons appointed by the Governor.

2. One person appointed by the President of the Senate.

3. One person appointed by the Speaker of the House of Representatives.

4. One person appointed by the Minority Leader of the Senate.

5. One person appointed by the Minority Leader of the House of Representatives.

All members must demonstrate knowledge and understanding of the ethical, medical, and scientific implications of embryonic and adult stem cell research and should also demonstrate knowledge of related fields, including, but not limited to, genetics, cellular biology, and embryology. At least three members shall have practical research experience in stem cell research or related fields. Members shall serve for terms of 4 years each commencing on October 1, 2006. No member shall serve for more than two consecutive 4-year terms. All initial appointments must be made by October 1, 2006. The first meeting shall take place no later than November 1, 2006. Members shall meet at least twice annually, but no more than four times annually. Members

shall serve without compensation but shall be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The oversight council shall review all embryonic or human adult stem cell research which is funded or supported in any manner through the Biomedical Research Trust Fund to ensure the adherence to ethical and safety guidelines and procedures as laid out by federal ethical standards established by the United States Department of Health and Human Services.

(6) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

(a) The Secretary of Health shall make grants-in-aid from the Biomedical Research Trust Fund in accordance with the provisions of this section.

(b) The Department of Health shall require any applicant for a grant-in-aid under this section, for the purpose of conducting stem cell research, to submit a complete description of the applicant's organization, the applicant's plans for stem cell research, the applicant's proposed funding for such research from sources other than the state, and the applicant's proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment, or similar rights resulting from any stem cell research made possible by the awarding of such grant-in-aid. The Biomedical Research Advisory Council shall provide recommendations to the Secretary of Health with respect to awarding such grants-in-aid after considering recommendations from the Biomedical Research and Ethics Oversight Council.

(c) Beginning with the 2006-2007 fiscal year, and for 10 consecutive years thereafter, not less than $15 million shall be

made available annually from the Biomedical Research Trust Fund for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research as directed by the Biomedical Research Advisory Council. Any balance of such amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid.

(7) FUNDING.--Funds provided under this section may only be used for research involving:

(a) Human adult stem cells, including, but not limited to, adult stem cells derived from umbilical cord blood and bone marrow.

(b) Human embryonic stem cells taken from donated leftover embryos from in vitro fertilization treatments that would otherwise be thrown away or destroyed.

1. A physician or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant, and appropriate information sufficient to allow the person to make an informed and voluntary choice regarding the disposition of any human embryos that remain following infertility treatment.

2. A person to whom information is provided pursuant to subparagraph 1. shall be presented with the options of storing any unused embryos, donating them to another person, donating the remaining embryos for research purposes, or selecting other means of disposition.

3. A person who elects to donate, for research purposes, any embryos remaining after receiving infertility treatment

shall provide written consent for that donation in a consent form provided by the Department of Health and made available to the public on the department's Internet website.

4. A person may not knowingly, for material or financial gain, purchase, sell, or otherwise transfer or obtain, or promote the sale or transfer of, embryonic fetal tissue for research purposes pursuant to this section. Embryonic and adult stem cell material may only be donated for research purposes with the informed consent of the donor. A person who violates any provision of this subparagraph commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(8) HUMAN REPRODUCTIVE CLONING; PROHIBITION; PENALTIES.--

(a) It is unlawful for any person to knowingly:

1. Perform or attempt to perform human reproductive cloning.

2. Participate or assist in an attempt to perform human reproductive cloning.

3. Ship or receive for any purpose an embryo produced by human reproductive cloning or any product derived from such embryo.

(b) A person who violates any provision of paragraph (a) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 4. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Sands offered the following:

Amendment (with directory and title amendments)

Remove line(s) 71-82 and insert:

Section 2. Subsections (2), (3), (4), and (5) of section 381.86, Florida Statutes, are renumbered as subsections (3), (4), (5), and (6), respectively, and a subsection (2) is added to that section, to read:

381.86 Institutional Review Board.--

(2) The Secretary of Health shall determine and appoint the membership of the board and designate its chair, except for research funded under s. 381.99 which shall have a separate review committee constituted as described in s. 381.99 for the sole purpose of reviewing research funded under s. 381.99.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment

Remove line(s) 94-95

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HB233-Sands2.doc

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment

Remove line(s) 108-109

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HB233-Sands3.doc

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 4 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment (with title amendments)

Remove line(s) 157-158 and insert:

(4) STEM CELL RESEARCH ADVISORY COUNCIL.--There shall be established a Stem Cell Research Advisory Council.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 11-12 and insert:

findings; creating the Stem Cell Research Advisory Council; providing for criteria, appointment, and terms of

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 5 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment (with title amendments)

Remove line(s) 250-255 and insert:

(5) STEM CELL ETHICS INSTITUTIONAL REVIEW BOARD.--There shall be established within the Florida Department of Health Institutional Review Board a separate committee that shall have oversight of the research conducted pursuant to s. 381.99. The board shall provide ethical oversight for stem cell research.

(a) For this committee only, there shall be seven members, of which the Secretary of Health or designee shall act as chair. The additional members shall be recommended to the Secretary for appointment as follows:

========== T I T L E A M E N D M E N T ==========

Remove line(s) 7-19 and insert:

within the jurisdiction of the Stem Cell Ethics Institutional Review Board; creating s. 381.99, F.S., the Florida Better Quality of Life and Biomedical Research Act; providing

Amendment No. 5 (for drafter's use only)

definitions; providing legislative findings; creating the Biomedical Research Advisory Council; providing for criteria, appointment, and terms of members; authorizing reimbursement for per diem and travel expenses; providing duties of the advisory council, including a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives; requiring the Department of Health to provide administrative support; creating the Stem Cell Ethics Institutional Review Board to regulate research

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 6 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment

Remove line(s) 275-276 and insert:

no later than November 1, 2006. Members shall meet at least twice a year or as often as necessary to discharge their duties but have no more than one meeting per month during any 12 month period. Members

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 7 (for drafter's use only)

Bill No. HB 233

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment

Remove line (s) 308 and insert:

directed by the Stem Cell Research Advisory Council. Up to 15 percent of the funds may be used for administrative costs. Any

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 8 (for drafter's use only)

Bill No. HB 233

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment

Remove line(s) 332 and insert:

any embryos remaining after receiving in vitro fertilization

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 9 (for drafter's use only)

Bill No. **HB 233**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sands offered the following:

Amendment (with title amendments)

Between line(s) 356-357 insert:

Section 4. The sum of $15,000,000 is appropriated from the General Revenue Fund to the Biomedical Research Trust Fund for the purposes of the Florida Better Quality of Life and Biomedical Research Act pursuant to s. 381.99, Florida Statutes, annually for the next 10 years.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 35-36 and insert:

reproductive cloning; providing penalties; providing an appropriation; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 243 Hearing Aid Specialists
SPONSOR(S): Kendrick and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 372

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Elder & Long-Term Care Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 243 excludes licensed hearing aid specialists from the requirement that a certain written statement of a patient's right to refuse or cancel payment, or be reimbursed for payment for other treatment or services, must accompany the advertisement of free and discounted services. The statement reads:

> "THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT."

Currently over fourteen other professions, such as naturopaths, dentists, and nurses, are required to make the above disclosure when advertising services that are free or provided at a reduced fee. However, audiologists, who also dispense hearing aids, are not included under s. 456.062, F.S., and do not have to publish a disclosure when advertising free or discounted services.

Hearing aid specialists and audiologists have numerous unique regulations, under part II of chapter 484 and part I of chapter 468, F.S., governing the dispensing of hearing aids such as a required thirty-day money back guarantee, price itemization, and hearing aid returns if a specified physician certifies that it is contraindicated.

Hearing aid specialists and audiologists often work in close contact with one another. Although audiologists are licensed to perform many more services than hearing aid specialists, one of their primary responsibilities is dispensing of hearing aids. Clinics that employ both hearing aid specialists and audiologists must include the disclosure in their advertisements when advertising services that are free or provided at a reduced fee, even though under s. 456.062, F.S., it is only required of hearing aid specialists. In Florida, there are currently 713 licensed hearing aid specialists and 783 licensed audiologists.[1]

HB 243 may lower advertising costs for hearing aid specialists and audiologists who employ hearing aid specialists. Hearing aid specialists and audiologists may choose to pass on their cost savings to customers.

The bill takes effect July 1, 2006.

[1] Florida Boards of Hearing Aid Specialists & Speech Language Pathology & Audiology, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill removes a regulation that requires hearing aid specialists to make a certain disclosure in their advertisements when advertising services that are free or provided at a reduced fee.

B. EFFECT OF PROPOSED CHANGES:

The bill amends s. 456.062, F.S., to exclude licensed hearing aid specialists from the requirement that a certain written statement must accompany the advertisement of free and discounted services. The statement reads:

> "THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT."

CURRENT SITUATION

Currently over fourteen other professions, such as naturopaths, dentists, and nurses, are required to make the above disclosure when advertising services that are free or provided at a reduced fee. However, audiologists, who also dispense hearing aids, are not included under s. 456.062, F.S., and do not have to publish a disclosure when advertising free or discounted services.

Hearing aid specialists and audiologists have numerous unique regulations, under part II of chapter 484 and part I of chapter 468, F.S., governing the dispensing of hearing aids such as a required thirty-day money back guarantee, price itemization, and hearing aid returns.

Hearing aid specialists and audiologists often work in close contact with one another. Although audiologists are licensed to perform many more services than hearing aid specialists, one of their primary responsibilities is dispensing of hearing aids. Clinics that employ both hearing aid specialists and audiologists must include the disclosure in their advertisements when advertising services that are free or provided at a reduced fee, even though under s. 456.062, F.S., it is only required of hearing aid specialists. In Florida, there are currently 713 licensed hearing aid specialists and 783 licensed audiologists.[2]

Hearing Aid Specialists

Hearing aid specialists are regulated under part II of chapter 484, F.S. Generally hearing aid specialists fit and sell hearing amplification systems to individuals in a retail establishment. Some of their duties include conducting hearing tests, interpreting auditory test results, and selecting, fitting, and modifying hearing amplification systems for individuals.

The Department of Health licenses each applicant that the Board of Hearing Aid Specialists certifies:

- Has completed the application form and remitted the required fees;
- Submits three letters of good moral character;
- Is 18 years of age;

[2] Florida Boards of Hearing Aid Specialists & Speech Language Pathology & Audiology, 2006.

- Is a graduate of an accredited high school or its equivalent;
- Submits two photographs;
- Meets either (1) or (2) below:
  (1) Has met the requirements of the Board of Hearing Aid Specialist training program; or
  (2) (a) Has a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing in such capacity for at least 12 months; or (b) Is currently certified by the National Board for Certification in Hearing Instrument Sciences and has been actively practicing for at least 12 months.
- Has passed the licensure examination, which is the International Licensing Examination (ILE) for the Hearing Instrument Dispenser.
- Has submitted a notarized laws and rules affidavit; and
- Has submitted proof of taking a two hour course on the prevention of medical errors.

Audiologists

Audiologists are regulated under part I of chapter 468, F.S. The practice of audiology includes the assessment of hearing and balance. Audiologists do research on hearing loss, tinnitus, and balance system dysfunction. Audiologists also select, fit, and dispense amplification systems such as hearing aids, prevent hearing loss through providing and fitting protective devices, provide consultation on the effects of noise on hearing, and provide consumer education.

The Department of Health licenses each applicant that meets the following requirements:

- Master's degree or Doctoral degree from an accredited college or university with a major emphasis in the area in audiology;
- Sixty (60) semester hours are required of which 30 semester hours must be at the graduate level;
- 300 clock hours in supervised clinical practice;
- Nine (9) months of professional employment;
- Passage of the national exam for active license;
- One (1) hour of HIV/AIDS training; and
- Two (2) hours in prevention of medical errors training.

Additionally, to maintain an active license applicants must have completed:
- A Master's degree or Doctoral degree from an accredited college or university audiology ;
- 30 semester hours in courses acceptable toward a graduate degree; and
- 200 supervised clinical hours in the discipline.

REGULATORY REQUIREMENTS FOR HEARING AID SPECIALISTS & AUDIOLOGISTS

Federal Regulations

Hearing aid specialists and audiologists are required to follow federal laws Title 21, Sec. 801.420 and 801.421 CFR. These laws cover:
- Federal hearing aid definitions;
- Labeling requirements for hearing aids;
- Medical evaluation requirements;
- Waiver to the medical evaluation requirements;
- Availability of hearing aid user instructional brochures; and
- Recordkeeping.

State Regulations

Thirty Day Trial Period

Sections 484.0512 and 468.1246, F.S., require that hearing aid specialists and audiologists must provide the buyer of a hearing aid with written notice of a 30-day trial period and money back guarantee. The guarantee must permit the purchaser to cancel the purchase for a valid reason. A valid reason is defined as, "failure by the purchaser to achieve satisfaction from use of the hearing aid(s), so long as the hearing aid(s) is returned to the seller within the 30-day trial period in good working condition.[3] If the hearing aid must be repaired, remade, or adjusted during the 30-day trial period, the running of the 30-day trial period is suspended 1 day for each 24-hour period that the hearing aid is not in the purchaser's possession. A repaired, remade, or adjusted hearing aid must be claimed by the purchaser within 3 working days after notification of availability. The running of the 30-day trial period resumes on the day the purchaser reclaims the repaired, remade, or adjusted hearing aid or on the 4th day after notification of availability.

Itemization of Prices

Sections 484.051 and 468.1245, F.S., require that hearing aid specialists and audiologists must provide an itemized listing of prices at the request of prospective hearing aid purchasers. This list must provide separate prices for each service component and each product.

Cancellation by Medical Authorization

Sections 484.0513 and 468.1255, F.S., gives hearing aid purchasers the right to their money back if the purchasers consults a licensed physician, with a specialty board certification in otolaryngology, internal medicine, or a licensed family practice physician, and the physician certifies in writing that the purchaser has a hearing impairment that contraindicates the use of a hearing aid or will not be improved by the use of a hearing aid. The purchaser must give notice to the seller via certified mail within 60 days following the date of delivery of the hearing aid.

Economics of Health Care Regulation

Economists argue that the regulation of health care usually involves striking a balance between patient safety and quality of care, and the cost and availability of services. Regulating quality is not without cost and it is not without an effect on the market for healthcare services. Regulations that increase the cost of providing health care may lead to increased prices, a decrease in quantity, and hurt the bottom line of the supplier of services, thus, limiting access to health care. If regulations increase the costs of health care too much, consumers may drop out of the market. The decrease in demand may then cause a chain reaction so that health care suppliers drop out of the market, which would limit access to health care (the supply). Even a policy aimed at increasing demand for service, may be constrained by regulatory policies that limit the ability for suppliers to respond, so that the effect may be a large increase in price and a smaller increase in quantity of services provided.[4]

C. SECTION DIRECTORY:

Section 1. Amends s. 456.062, F.S., to exclude a licensed hearing aid specialist from having to publish a disclaimer statement with all advertisements of free or discounted services.

Section 2. Provides an effective date of July 1, 2006.

[3] 64B6-6.001(2) F.A.C & 64B30-8.008 (3), F.A.C.

[4] Health Care Issues Associated with Regulation, Presentation to House Committee on Health Care Regulation, March 2005, Steve Ullmann, Ph.D., University of Miami.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate **[See D. Fiscal Comments]**

D. FISCAL COMMENTS:

HB 243 may lower advertising costs for hearing aid specialists and audiologists who employ hearing aid specialists. Hearing aid specialists and audiologists may choose to pass on their cost savings to customers.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule making authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Board of Hearing Aid Specialists has stated that audiologists, who also sell hearing aids, are not subject to this same advertising disclosure requirement in s. 456.062, F.S. Placing hearing aid specialists in this category with other health professionals, when they also must offer trial periods, refunds and money back guarantees, may be duplicative or unnecessary.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to hearing aid specialists; amending s. 456.062, F.S.; eliminating the application of certain advertising requirements to health care practitioners licensed under pt. II of ch. 484, F.S., relating to the regulation of hearing aid specialists; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.062, Florida Statutes, is amended to read:

456.062 Advertisement by a health care practitioner of free or discounted services; required statement.--In any advertisement for a free, discounted fee, or reduced fee service, examination, or treatment by a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, chapter 467, chapter 478, chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491, the following statement shall appear in capital letters clearly distinguishable from the rest of the text: THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT. However, the required statement shall not be

necessary as an accompaniment to an advertisement of a licensed health care practitioner defined by this section if the advertisement appears in a classified directory the primary purpose of which is to provide products and services at free, reduced, or discounted prices to consumers and in which the statement prominently appears in at least one place.

Section 2. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 483 Nursing Services
SPONSOR(S): Garcia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Insurance Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 483 provides that a registered nurse shall function in an operating room as a circulating nurse during all operative or invasive procedures. The bill provides that a "circulating nurse" is a registered nurse who is responsible for coordinating all nursing care, patient safety needs, and the needs of the surgical team in the operating room.

Currently, Ambulatory Surgical Centers, licensed by the Agency for Health Care Administration, are required to have a registered nurse serve as an operating room (OR) circulating nurse (59A-5.0085, F.A.C.). Florida is one of seven states that do not have specific staffing requirements for hospital operating rooms. This bill requires hospitals to have registered nurses perform as circulating nurses in operating rooms. Currently, federal law provides that LPNs and surgical techs may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, but does not require circulatory duties be performed by a registered nurse (42 CFR Part 482).

Fiscal Impact: This bill does not appear to have a fiscal impact on state or local governments.

The bill shall take effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill increases governmental regulation of a licensed profession and hospital.

B. EFFECT OF PROPOSED CHANGES:

Currently, Ambulatory Surgical Centers, licensed by the Agency for Health Care Administration, are required to have a registered nurse serve as an operating room (OR) circulating nurse.[1] Florida is one of seven states that do not have specific staffing requirements for hospital operating rooms. This bill requires hospitals to have registered nurses perform as circulating nurses in operating rooms. Currently, federal law provides that LPNs and surgical techs may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, but does not require circulatory duties be performed by a registered nurse.

PRESENT SITUATION

According to the Association of periOperative Registered Nurses (AORN), operating room (OR) nurses are now referred to as perioperative registered nurses to more accurately reflect their duties immediately before, during, and after surgery.[2] Section 464.027(2)(a), F.S., provides a definition of "perioperative nursing" to mean a practice of nursing in which the nurse provides preoperative, intraoperative, and postoperative nursing care to surgical patients.

Operating Room Nursing Staff

There are several roles performed by nurses in the operating room.

Registered nurse (RN) first assistant
The registered nurse first assistant (RNFA) directly assists the surgeon, often directly opposite the operating table during a procedure. The RN first assistant duties, conducted under the supervision of the surgeon, can be as basic as tying sutures, knots and performing skin closures to assisting in complex surgical procedures.[3] To practice as a RN first assistant, a nurse must first obtain certification as a perioperative nurse (CNOR) and then attend a RN first assistant program.

- A **perioperative nurse** must have a minimum of 2 full years and 2,400 hours of operating room practice as a registered nurse; been employed within the previous 2 years, either full-time or part-time as a registered nurse in an administrative, teaching, research, or general staff capacity in perioperative nursing.
- A **certified RN first assistant** must be certified as a perioperative nurse; must document 2,000 hours of practice in the RN first assistant role, with at least 500 hours in the past 2 years; must have attended a formal RN first assistant program; and have a bachelors degree in nursing.[4]
- In Florida, a **registered nurse assistant** must attend one academic year, or 45 hours of didactic instruction and 120 hours of clinical internship; licensed as a registered nurse; certified

[1] See 59A-5.0085, F.A.C.
[2] Association of periOperative Registered Nurses, *It's important for you to know...*, available at http://www.aorn.org/About/important.htm (January 11, 2006).
[3] Saunders, Kate. 2006. Advance Online Editions for Nurses. *Growth in the OR: The role of the registered nurse in surgery has grown and changed with technological advances.*
[4] Nursing Center, *Certification,* available at http://www.nursingcenter.com/prodev/ce_certification.asp (January 17, 2006).

as a perioperative nurse; and hold a certificate from a recognized registered nurse first assistant program.[5]

Scrub nurse

The scrub nurse works directly with the surgeon within the sterile field, passing instruments, sponges, and other items needed during the surgical procedure. The sterile field is the area closely surrounding the OR table and the instrument tray. Surgical team members who work within the sterile field have scrubbed their hands and arms with special disinfecting soap and wear surgical gowns, caps, gloves, shoe covers, and eyewear.[6] A scrub nurse position may be filled by a RN, a licensed practical nurse (LPN), or a surgical tech.

Circulating nurse

The circulating nurse's duties are performed outside the sterile field. The circulating nurse is responsible for managing the nursing care within the OR and performs such duties as prepping the patient, retrieving instruments, procedure documentation, dispensing medications, implementing an individualized care plan, and evaluating patient outcomes.[7] The circulating nurse observes the surgical team from a broad perspective and assists the team to create and maintain a safe, comfortable environment. The circulating nurse makes sure each member of the surgical team performs in a united effort. Currently, Florida statute does not specify the professional requirements for circulating nurses.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Prior to 1994 the Accreditation Manual for Hospitals (AMH), required that "A qualified registered nurse is assigned to circulating nurse duties for the operating room and for the obstetric delivery room." The AMH further stated, "Other qualified operating room personnel assisting in circulating duties in the operating room and in the obstetrical delivery room are under the supervision of a qualified registered nurse who is immediately available."

In 1994, the AMH revised their manual and deleted this requirement (and limitation). At the time, a Joint Commission spokesperson stated that "Determination of actual staffing is hospital specific," adding that, "If a hospital determines...that certified surgical technologists have the necessary qualifications and competencies to perform the anticipated job responsibilities, and applicable licensure, law, and regulation, and/or certification is consistent with or does not preclude such, the intent ...will be met." [8]

Centers for Medicare and Medicaid Services

Centers for Medicare and Medicaid Services (CMS), is the federal agency that administers the Medicare, Medicaid and Child Health Insurance Programs. CMS regulations state that hospitals must be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation(CoPs), in 42 CFR Part 482, in order to receive Medicare/Medicaid payment. The CoPs state that:[9]

- Hospitals must have an organized nursing service that provides 24-hour nursing services. The services must be furnished or supervised by a registered nurse.[10]
- The operating room must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.[11]

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[5] See s. 464.027, F.S.

[6] Association of periOperative Registered Nurses, *It's important for you to know...*, available at http://www.aorn.org/About/important.htm (January 11, 2006).

[7] Saunders, Kate. 2006. Advance Online Editions for Nurses. *Growth in the OR: The role of the registered nurse in surgery has grown and changed with technological advances.*

[8] "Circulating Assignment in Operating Room Clarified," Joint Commission Perspectives. Joint Commission on Accreditation of Healthcare Organizations, 1996, p 20.

[9] The Health Care Financing Administration, *Survey Protocol,* available at http://new.cms.hhs.gov/manuals/downloads/som107ap_a_hospitals.pdf (January 10, 2006).

[10] 42 CFR Part 482.23

- Licensed practical nurses (LPNs) and surgical technologists (OR techs) may serve as "scrub nurses" under the supervision of a registered nurse.[12]
- Qualified registered nurses may perform circulating duties in the operating room.
- LPNs and surgical techs may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately[13] available to respond to emergencies.[14]

State laws and regulations can be more stringent than CMS regulations, and patient care must be furnished consistent with State law.

State Regulations

State governments regulate all occupations and professions, and it is within the power of state governments to ensure patient safety through the regulation of occupations.[15] According to a report by the Association of periOperative Registered Nurses (AORN):

- 20 states require RNs to circulate,
- 37 states require RNs to supervise in the OR but do not specifically mention the role of circulating nurse,
- 8 states explicitly follow Health Care Financing Administration's conditions of participation for surgical services, and
- 7 states have no specific staffing requirements.

Currently, Florida is one of seven states that have no nurse staffing requirements for hospital operating rooms (ORs). The other states are Georgia, Louisiana, Maryland, Ohio, Washington, and West Virginia. Of the 20 states that require an RN to circulate, California, Idaho, Maine, and Nevada require adequate staffing so that each RN does not circulate for more than one operating room. Hawaii, Oklahoma, Utah, and Wyoming mandate that licensed practical nurses (LPNs) and surgical technologists cannot function as the circulating nurse in the operating room. In Indiana, Nebraska, New Mexico, and Wisconsin, LPNs and surgical technologists may function as assistants under the direct supervision of a qualified RN.[16]

The eight states (i.e., Alabama, Indiana, Iowa, Massachusetts, Montana, North Dakota, New York, and Texas) that explicitly follow Health Care Financing Administration rule governing surgical services also mandate that LPNs and surgical technologists may assist in circulatory duties under the direct supervision of a qualified RN, who is immediately available to respond to emergencies.[17]

Health Care Regulation Policy Concerns

Section 11.62(3), F.S., requires the Legislature to consider the following factors in determining whether to regulate a new profession or occupation:

- That a profession or occupation is not subjected to regulation by the state unless the regulation is necessary to protect the public's health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; and

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[11] 42 CFR Part 482.51(a)(1)
[12] 42 CFR Part 482.51(a)(2)
[13] According to CMS, the supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical tech.
[14] 42 CFR Part 482.51 (a)(3)
[15] AORN Journal: May 2001 Health Policy Issues, *The critical "nurse" in the circulating nurse role*, available at http://www.aorn.org/journal/2001/mayhpi.htm (January 10, 2005).
[16] Ibid.
[17] Ibid.

- That a profession or occupation is not regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

Economists argue that the regulation of health care usually involves striking a balance between patient safety and quality of care, and the cost and availability of services. Regulating quality is not without cost and it is not without an effect on the market for healthcare services. Regulations that increase the cost of providing health care may lead to increased prices, a decrease in quantity, and hurt the bottom line of the supplier of services, thus, limiting access to health care.[18]

Patient Safety and Scope of Practice

According to the Association of periOperative Registered Nurses (AORN), although unlicensed professionals may possess the technical skills to circulate, they do not have the ability to apply the nursing process to perioperative patient care. AORN further claims that to ensure patient safety, an RN must fill the role of the circulator.

C. SECTION DIRECTORY:

Section 1. Amends s. 395.0191, F.S., provides that certain nurses must be present in operating rooms and function as circulating nurses and defines the term "circulating nurse."
Section 2. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals may experience a fiscal impact in implementing the provisions of this bill. Hospitals that currently allow LPNs or surgical techs perform as "circulating nurses" will have to hire registered nurses to perform the duties of a circulating nurse. According to a 2004 National survey, registered nurses average $19.33 per hour, while licensed practical nurses average $13.58 per hour.[19]

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[18] Health Care Issues Associated with Regulation, Presentation to House Committee on Health Care Regulation, March 2005, Steve Ullmann, Ph.D., University of Miami.
[19] Nursing2004, *Nursing 2004 salary survey*, available at http://www.findarticles.com/p/articles/mi_qa3689/is_200410/ai_n9431354

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to nursing services; amending s. 395.0191, F.S.; requiring certain nurses to be present in operating rooms and function as circulating nurses during all operative or invasive procedures; defining the term "circulating nurse"; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (d) is added to subsection (2) of section 395.0191, Florida Statutes, to read:

395.0191 Staff membership and clinical privileges.--

(2)

(d) A registered nurse licensed under part I of chapter 464 and qualified by training and experience in operating room nursing shall be present in the operating room and function as the circulating nurse during all operative or invasive procedures. For the purposes of this paragraph, the term "circulating nurse" means a registered nurse who is responsible for coordinating all nursing care, patient safety needs, and the needs of the surgical team in the operating room during an operative or invasive procedure.

Section 2. This act shall take effect July 1, 2006.

Addendum

Health Care Regulation Committee

Wednesday, January 25, 2006
9:30 AM - 12:00 PM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

OFFICE OF INSURANCE REGULATION

FAIR. FAST. PROFESSIONAL.

Discount Medical Plan Organizations (DMPOs)

David Foy
Florida Office of Insurance Regulation

January 25, 2006

200 East Gaines Street, Tallahassee, FL 32399
(850) 413-3140

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2005 Georgetown University Study

- Health Policy Institute Project
- Tested 5 cards in the Washington, D.C. area
- 1 of the 5 cards delivered the advertised discounts
- 2 out of the 5 cards - unable to find any doctors or hospitals that would meet the levels of advertised discounts.

OFFICE OF INSURANCE REGULATION

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Consumer Reported Problems and Complaints

- Consumers were paying for the discount plans, but not receiving the plan packages so they can utilize services

- Consumers were being charged with non-refundable application fees.

- The doctors and hospitals were not recognizing the identification cards consumers were given upon enrollment.

- Requests for terminating drafts on credit card accounts and bank accounts were not being honored.

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(850) 413-3140

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Problems and Complaints (continued)

- Licensed insurance agents were selling the discount plans
- Requirements such as 7-day notices for office visits and 30-day notices for hospitalizations in order for a consumer to receive the discount.
- Advertisements were using health insurance terminology.

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Discount medical plan organization – is defined as "an entity which, in exchange for fees, dues, charges, or other consideration, provides access for plan members to providers of medical services and the right to receive medical services from those providers at a discount."

Discount medical plan – is defined as "a business arrangement or contract in which a person, in exchange for fees, dues, charges, or other consideration, provides access for plan members to providers of medical services and the right to receive medical services from those providers at a discount."

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OFFICE OF INSURANCE REGULATION

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The New DMPO Law in Florida

- Creates definitions on discount medical plan, plan organizations, marketers, medical services, providers, members, etc.
- Requires a discount medical plan to be licensed prior to conducting business
- Requires an annual licensure fee of $50 per license
- Provides the Office with examination and investigation authority
- Provides that DMPOs may charge a periodic amount as well as a one-time processing fee
- Provides disclosures to the consumer
- Prohibits certain activities of the DMPOs – related to advertisements, marketing materials, etc.

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Florida DMPO Law (cont.)

- Requires written provider agreements between the DMPOs and provider
- Rates must be filed with the Office and any rates of $30 per month, or $360 per year must be approved, in advance, by the Office
- All forms, or policy contracts, must be filed and approved, in advance, with the Office
- Requires an annual report that includes audited financial statements, the number of enrolled members, and other miscellaneous information
- Requires DMPOs to have minimum capital requirements and maintain a net worth of $150,000
- Provides the Office with suspension and revocation powers

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Florida DMPO Law (cont.)

- Provides the Office with administrative penalty powers for violations of law
- Requires each DMPO to maintain a surety bond or security deposit in order to protect financial interests of members
- Requires DMPOs to have written agreements with any marketers selling, promoting or distributing the plan
- Creates criminal penalties for individuals who willfully violate the law

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Current DMPO Environment

- Consumer Complaints in 2005: 111
- Of the 60 known DMPOs
  - 56 have filed an application for licensure
  - 38 have been granted a Certificate of Authority
  - 42 have filed forms and rates (31 have approved filings)
- The Office has received a total of 293 filings.
  - A total of 156 have been approved
  - 35 are currently pending.
- The Office has three FTE positions allocated to the DMPO regulations

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Future Considerations

National Topics of Discussion

1. Bundling of Products
2. Operations in Florida – Sales to Non-Florida Residents

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